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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,585	03/10/2000	Christopher G M Ken	290252020501	5888

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EXAMINER
PHANIJPHAND, GWEN G

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/523,585	Applicant(s) KEN ET AL.
	Examin r Gwen Phanijphand	Art Unit 3731

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO AMENDMENT

Claim Rejections – 35 U.S.C. 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 31, 32, 33, 35, and 37 through 44 are rejected under 35 U.S.C 102(b) as being clearly anticipated by U.S. Patent No. 5,354,295 to Guglielmi et al.

Regarding claim 31, Guglielmi et al. disclose in Fig. 3 a retainer deliverable via a tubular device (44) comprising a core wire (42) and a joint (elements 50 or 54: both joints), which is electrolytically severable upon application of a current (col. 5, ll. 44-47 and col. 6, ll. 19-20). Both joints, 50 and 54, extend between the distal end of the core wire and at least one array element (56). Guglielmi further discloses a retainer assembly (elements 56 and 58) comprising at least one array element (56). In Figs. 7 and 8, the retainer assembly has a first shape when retained within the tubular device (col. 4, ll. 33-37) and a second shape when retainer assembly is not retained in tubular device (col. 4, ll. 44-46) wherein at least one array element extends outwardly from the joint in the second shape. In Fig. 5, the second shape is configured for retaining a vaso-occlusive device in an aneurysm. A coil can be introduced and the device of Guglielmi et al. is capable of retaining the coil(s). It is well-known to introduce coils with devices such as the device of Guglielmi et al. (see Abstract of U.S. Patent. No. 5,639,277 to Mariant et al.). After electrolytic severance from core wire, the retainer assembly includes a residual joint (Fig. 5: element 46).

Regarding claim 32, Guglielmi et al. disclose the core wire covered with an electrical insulation layer (col. 6, ll. 20-21).

Regarding claim 33, Guglielmi et al. disclose at least one array element comprising platinum (col. 7, line 67).

Regarding claim 35, Guglielmi et al. disclose at least one array element comprising stainless steel (col. 7, line 35).

Regarding claim 37, Guglielmi et al. disclose a portion of at least one array element covered by radio-opaque material (col. 4, ll. 29-30).

Regarding claim 38, Guglielmi et al. disclose the radio-opaque material being platinum (col. 4, ll.29-30, col. 7, l. 67).

Regarding claim 39, Guglielmi et al. disclose in Fig. 4 that when the retainer assembly is in the second deployed shape, at least one array element terminates from the joint (54). In Fig. 3, the array element (56) terminates at the joint (54)

Regarding claim 40, Guglielmi et al. disclose in Fig. 3 that when the retainer assembly is in second shape, the residual joint, which would be the portions between 50 and 54, is distal to the proximal deployed end.

Regarding claim 41, Guglielmi et al. disclose in Fig. 4 that when the retainer assembly is in the second shape, the residual joint is on the proximal deployed end.

Regarding claim 42, Guglielmi et al. disclose in Fig. 4 the proximal deployed end is distal to the proximal delivery end when the retainer is in the second deployed shape.

Regarding claim 43, Guglielmi et al. disclose in Figs. 4 and 5 the secondary deployed shape approximating the shape of vascular aneurysm.

Regarding claim 44, Guglielmi et al. disclose in Figs. 1A and 4 the retainer assembly enclosing a volume and wherein the retainer contains a helically wound vaso-occlusive device.

(col. 9, ll. 21-23). A coil can also be introduced wherein the device of Guglielmi et al. is capable of retaining the coil. It is well-known to introduce coils with devices such as the device of Guglielmi et al. (see Abstract of U.S. Patent. No. 5,639,277 to Mariant et al.).

Claim Rejections - 35 U.S.C. 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guglielmi et al. in view of U.S. Patent No. 5,639,277 to Mariant et al.

Regarding claim 34, Guglielmi et al. disclose an implantable retainer but do not disclose at least one array element comprising of tantalum. Mariant et al., however, disclose an analogous device using tantalum (col. 1, ll.53-55; col. 4, ll.13-18) in its composition. The use of tantalum is advantageous because of its radiopaque property, which allows one to observe and monitor the device's position. It is well known to compose a device out of radiopaque material for observation and would have been obvious to one of ordinary skill in the art at the time of the invention to compose an array element of Guglielmi et al. from tantalum as in Mariant et al. because this allows the array element to be supervised from outside the body.

Regarding claim 36, Guglielmi et al. disclose an implantable retainer but do not disclose at least one array element comprising of a super-elastic alloy. Mariant et al., however, disclose an analogous device composed of a variety of materials. In col. 3, ll.66-67 and col.4, ll.1-3, 13-15, Mariant et al. disclose alloys and elastic polymers such as polyethylene as being suitable materials for composing an array element. These materials are advantageous because they are biocompatible and flexible, which are both necessary for forming a vasoocclusion. It is well

known to compose an array element used in blood vessel of a super-elastic alloy and would have been obvious to one of ordinary skill at the time of the invention to compose the array element of Guglielmi et al. from a super-elastic alloy as in Mariant et al. so that the array element would conform to the vessel and be biocompatible.

Response to Arguments

3. Applicant's arguments with respect to claim 31 have been considered but are moot in view of the new ground of rejection. Regarding claim 31, the retainer assembly comprises *at least one array element*, which the device of Guglielmi et al. comprises. The device of Guglielmi et al. is also configured for retaining a vaso-occlusive device in an aneurysm. A coil can be introduced and the device of Guglielmi et al. is capable of retaining the coil(s). This is well-known and described in the Abstract of U.S. Patent. No. 5,639,277 to Mariant et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijphand whose telephone number is 703-305-4845. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP
February 20, 2003 GP

Gwen Phanijphand
Patent Examiner
Art Unit 3731

Michael J. Milano
Supervisory Patent Examiner
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